SRI ORION PHARMACEUTICALS & SUTURES

21/22, 1st Cross, Ganesh Block, Nandini Layout, BANGALORE 560096
✆ : 349 8093 Fax : 91 80 359 3958 E mail : orion_suture@yahoo.com

K030177

JUL 2 1 2003

3.0 SUMMARY OF SAFETY AND EFFECTIVENESS

3.1 SPONSOR IDENTIFICATION

S. Gururajarao
Sri Orion Pharmaceuticals & Sutures
21/22, 2nd Floor, 1st Cross, Ganesh Block
Nandini Layout
Bangalore-560096
India
Telephone: 91 80 3498093
Fax: 91 80 359 3958
Orion_suture@yahoo.com

3.2 ESTABLISMENT REGISTRATION NUMBER: PENDING

3.3 OFFICIAL CONTACT PERSON AND AGENT

Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group Inc.
9109 Copenhaver Drive
Potomac, MD 20854
Tel: 301-279-2899
FAX: 301-294-0126
estrin@yourFDAconsultant.com

3.4 DATE OF PREPARATION: January 14, 2003

3.5 DEVICE NAMES

3.5.1 Trade Name: ORLON®

3.5.2 Common or Usual Name: Polyamide Surgical Suture

3.5.3 Classification Name: Nonabsorbable Polyamide Surgical Suture (21CFR 978.5020)

3.6 PROPOSED REGULATORY CLASS: Class II

3.7 DEVICE PRODUCT CODE: GAR

3.8 CFR REFERENCE: 21CFR 878.5020

3.9 PANEL : General & Plastic Surgery

3.10 DEVICE DESCRIPTION

The **ORLON® NONABSORBABLE SURGICAL SUTURE USP** is a polyamide suture. It is a nonabsorbable, sterile, flexible thread that is prepared from long-chain aliphatic polymers Nylon 6 and Nylon 6,6. It meets all the requirements established by the United States Pharmacopoeia for nonabsorbable sutures. It is offered in the monofilament form and is dyed with an appropriate FDA listed color additive. The suture is provided uncoated and with or without a standard needle attached.

3.11 INDICATIONS FOR USE

The **ORLON® Polyamide Nonabsorbable Needle Suture USP** (Polyamide filament) is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

3.12 PREDICATE DEVICE COMPARISON

The **ORLON® Polyamide Nonabsorbable Needle Suture USP** is substantially equivalent to the NYLON Polyamide Surgical Suture (K993998) submitted by Trading Consultants and Distributors International Inc., 157 Wind Dance Drive, Chicago, IL 60046-6681 and the Surgilon® Nonbsorbable Surgical Suture submitted by Sherwood-Davis & Geck.

Both the **ORLON®** Polyamide Nonabsorbable Needle Suture USP and the predicate devices are nonabsorbable polyamide sutures and are sold in the monofilament form and have the same indications for use. Both the **ORLON®** product and the NYLON product meet the requirements of the United States Pharmacopoeia.

3.13 SUMMARY OF STUDIES

All the testing and the manufacturing process conform to the standards of the United States Pharmacopoeia. After sterilization, the sutures are subjected to physical tests of diameter, tensile strength, needle attachment and sterility. Once all these tests are conducted and the sutures pass these tests, they are released for distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1 2003

Sri Orion Pharmaceuticals & Sutures
c/o Norman F. Estrin, Ph.D., RAC
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K030177
Trade/Device Name: The ORLON® Polyamide Nonabsorbable Needle Suture USP
Regulation Number: 21 CFR 878.5020
Regulation Name: Suture, nonabsorbable, synthetic, polyamide
Regulatory Class: II
Product Code: GAR
Dated: June 15, 2003
Received: June 16, 2003

Dear Dr. Estrin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030177

510(k) Number (if known):

Device Name: The ORLON® Polyamide Nonabsorbable Needle Suture USP

Indications for Use:

The ORLON® Polyamide Nonabsorbable Needle Suture USP (Polyamide filament) is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030177